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Martinez

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(54) **CLIP DEVICES AND METHODS OF DELIVERY AND DEPLOYMENT**

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A61B 17/128 (2006.01)
A61B 17/122 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/1285*** (2013.01); ***A61B 17/1227*** (2013.01)

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CPC A61B 17/0487; A61B 17/1285; A61B 17/122; A61B 2017/1227; A61B 17/128
USPC 606/139, 142, 143, 151, 157
See application file for complete search history.

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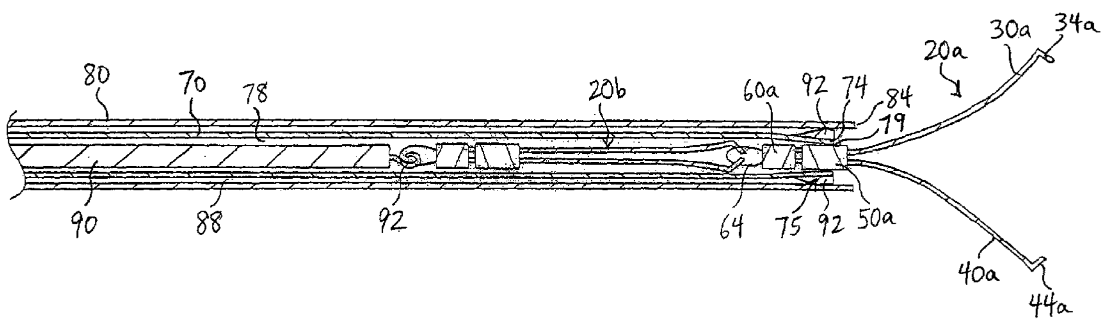
(57) **ABSTRACT**

The present embodiments provide systems and methods for deploying at least one clip device. In a first embodiment, the system comprises a first clip device having first and second arms. The first clip device and an associated sliding ring are configured to be selectively advanced through a lumen of an inner catheter. Selective positioning of an outer catheter over a distal region of the inner catheter causes a distal region of the inner catheter to bow radially inward to form a constriction that securely engages the sliding ring of the first clip device, thereby allowing for partial closure and repositioning of the first clip device. In an alternative embodiment, a delivery system includes a single catheter having a tapered distal region, such that upon ejection of the sliding ring from the distal end of the catheter, the sliding ring is dimensioned to abut the distal end of the catheter. In any of the embodiments, multiple clips may be sequentially loaded and deployed using the delivery systems. Various clip designs and a loading cylinder are also disclosed.

20 Claims, 6 Drawing Sheets



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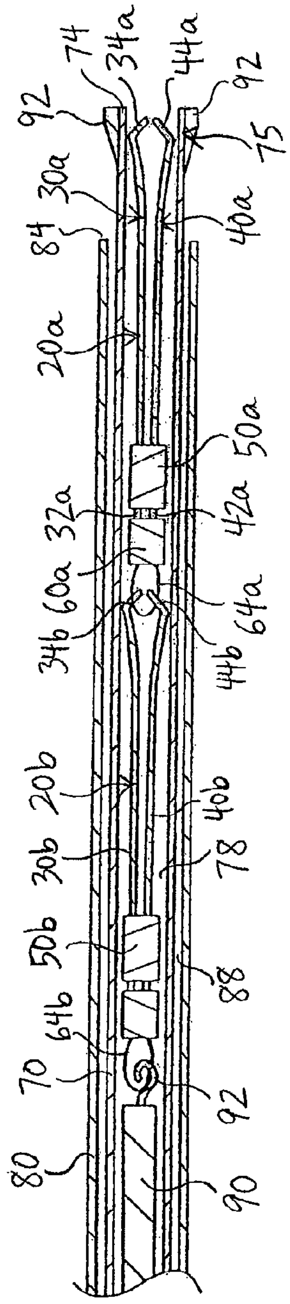
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42a
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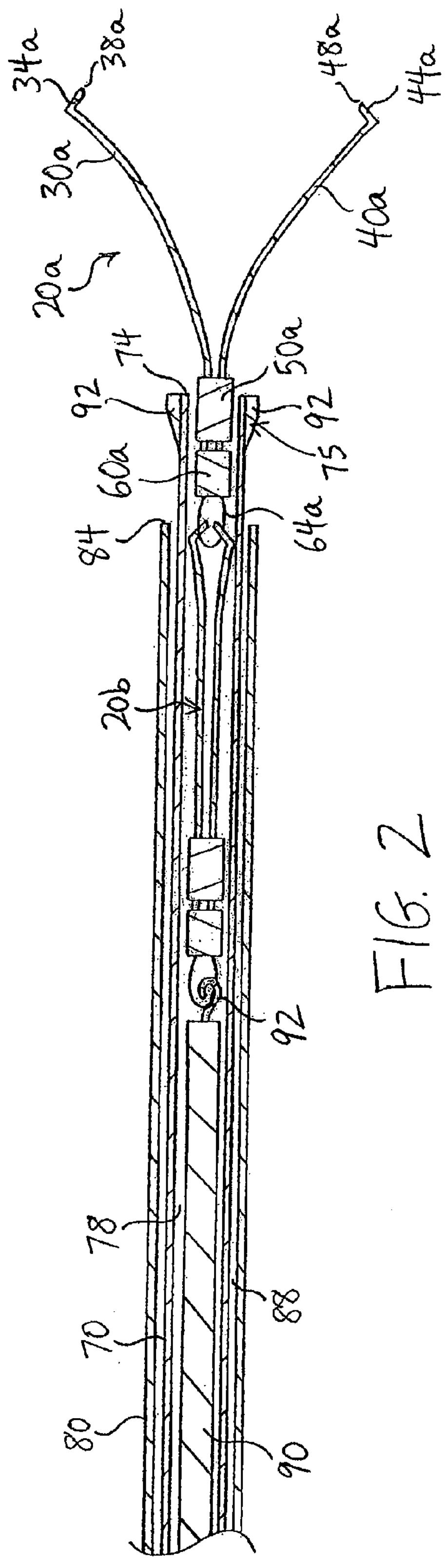
70
92
80
90

FIG. 1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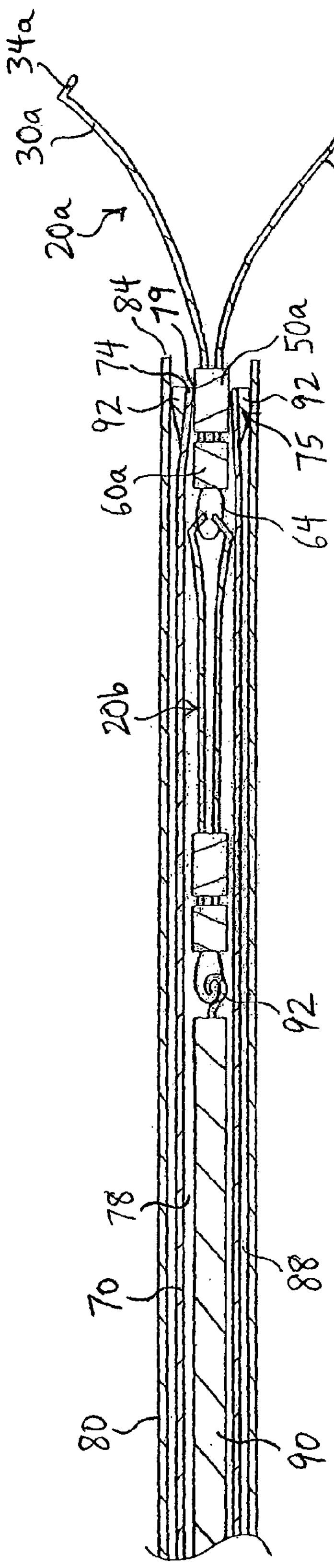
90

FIG. 2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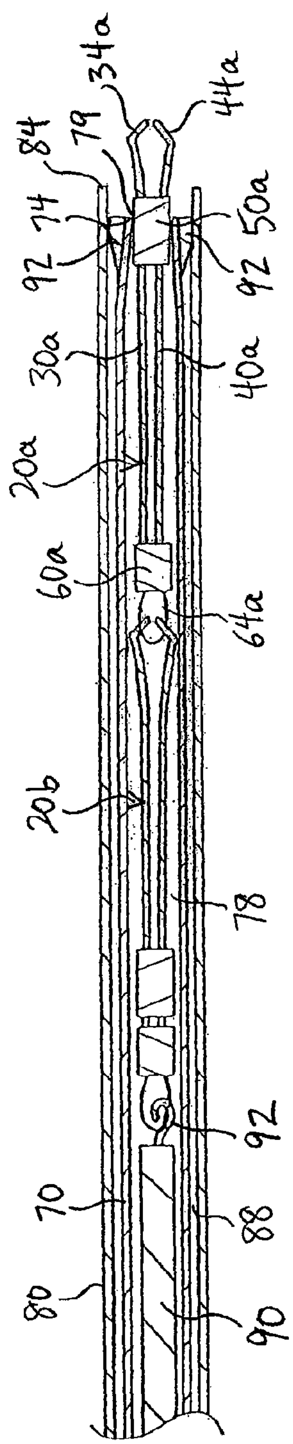
80
90

FIG. 3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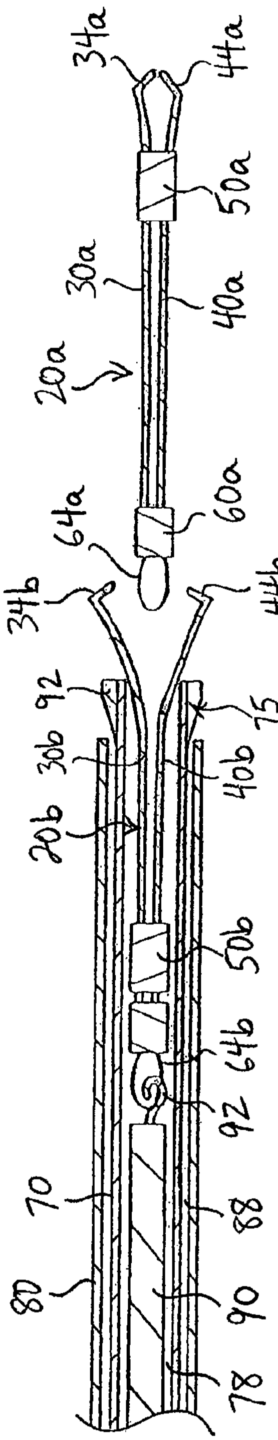
90

FIG. 4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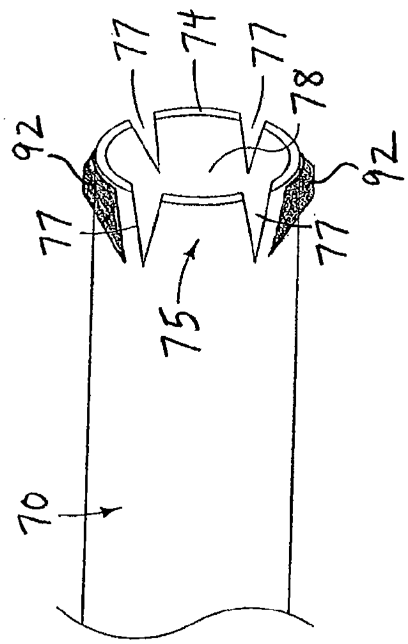
90
78

FIG. 5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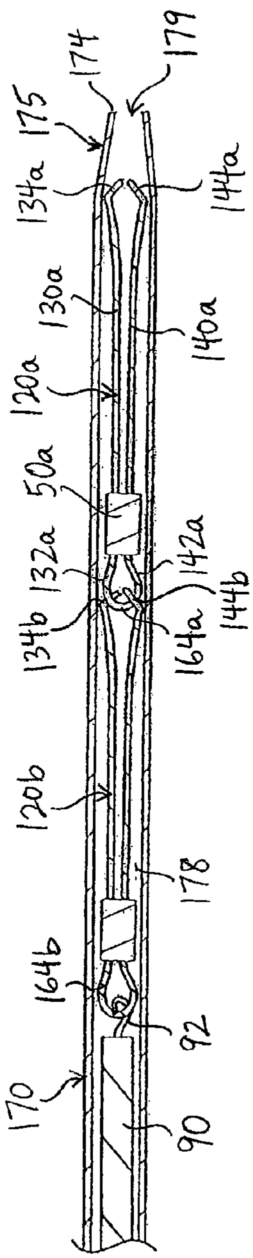
77
75
70

FIG. 6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134b
144b
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164b
92
170
90

FIG. 7

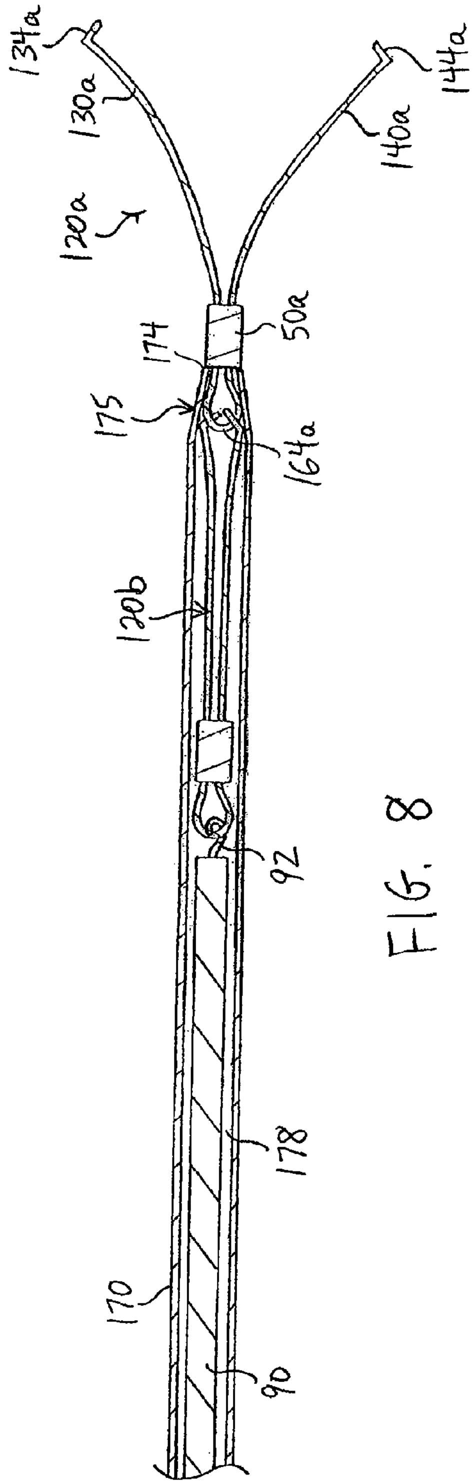
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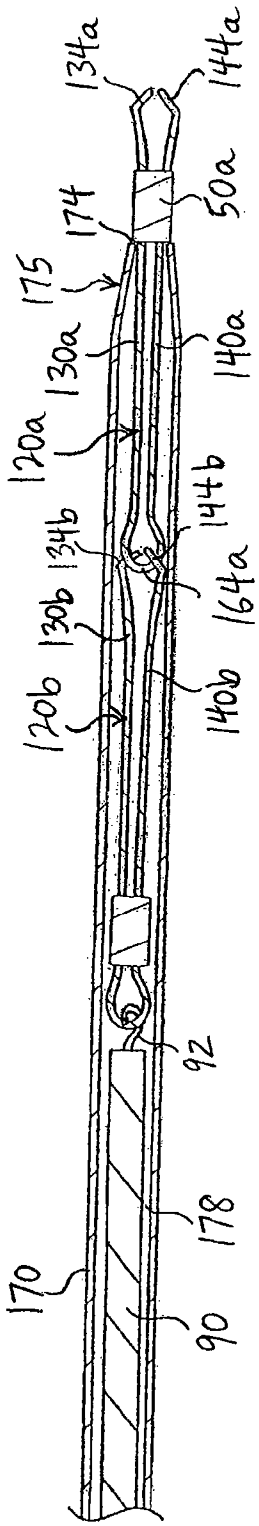
FIG. 8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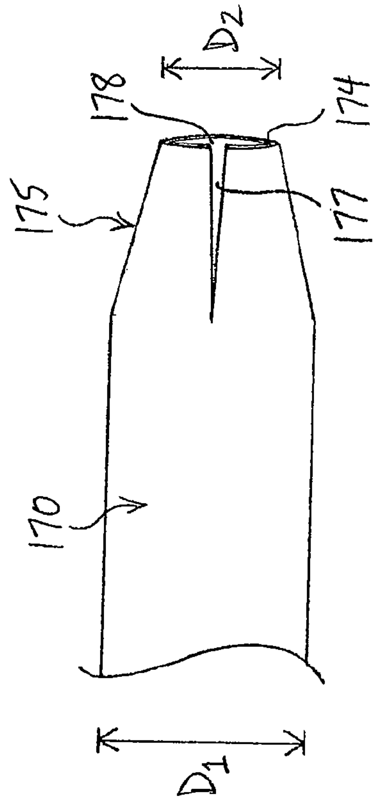
90

FIG. 9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D1

FIG. 10

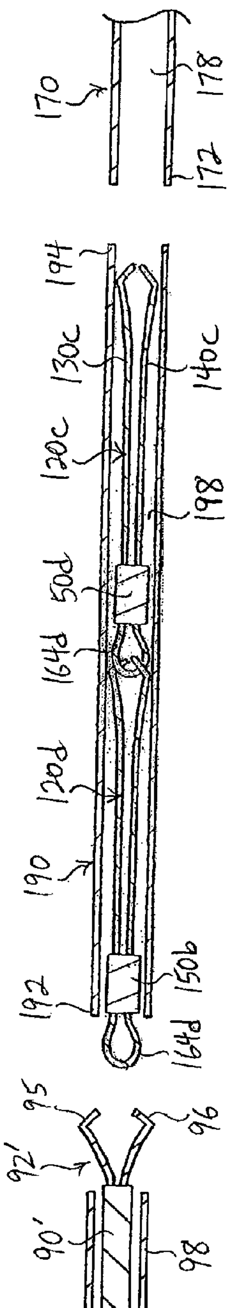

FIG. 11

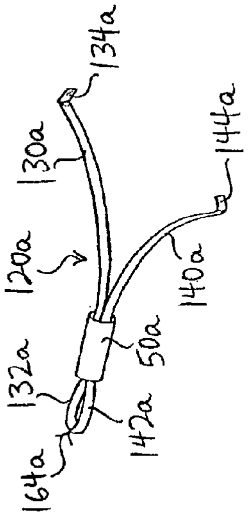

FIG. 12

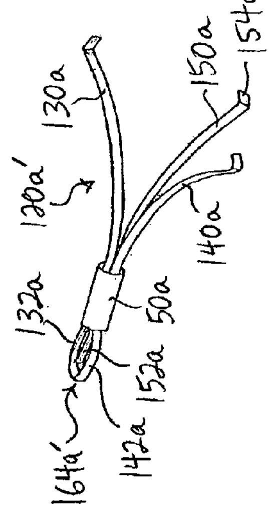

FIG. 13

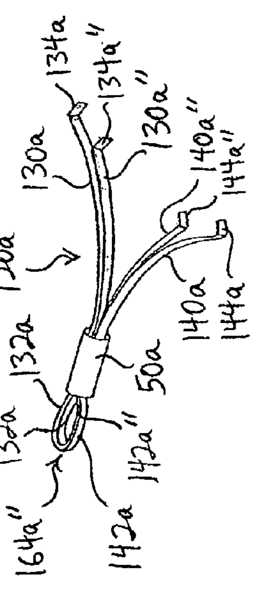

FIG. 14

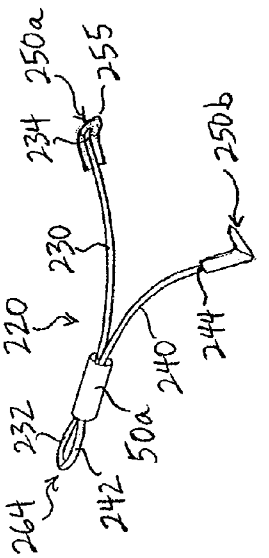

FIG. 15

CLIP DEVICES AND METHODS OF DELIVERY AND DEPLOYMENT

PRIORITY CLAIM

This invention claims the benefit of priority of U.S. Provisional Application Ser. No. 61/372,283, entitled "Clip Devices and Methods of Delivery and Deployment," filed Aug. 10, 2010, the disclosure of which is hereby incorporated by reference in its entirety.

BACKGROUND

Conventionally, a clip may be introduced into a body cavity through an endoscope to grasp living tissue of a body cavity for hemostasis, marking, and/or ligating. In addition, clips are now being used in a number of applications related to gastrointestinal bleeding such as peptic ulcers, Mallory-Weiss tears, Dieulafoy's lesions, angiomas, post-papillotomy bleeding, and small varices with active bleeding.

Gastrointestinal bleeding is a somewhat common and serious condition that is often fatal if left untreated. This problem has prompted the development of a number of endoscopic therapeutic approaches to achieve hemostasis such as the injection of sclerosing agents and contact thermo-coagulation techniques. Although such approaches are often effective, bleeding continues for many patients and corrective surgery therefore becomes necessary. Because surgery is an invasive technique that is associated with a high morbidity rate and many other undesirable side effects, there exists a need for highly effective, less invasive procedures.

Mechanical hemostatic devices have been used in various parts of the body, including gastrointestinal applications. Such devices are typically in the form of clamps, clips, staples and sutures, which are able to apply sufficient constrictive forces to blood vessels so as to limit or interrupt blood flow. One of the problems associated with conventional hemostatic devices, however, is that many devices are not strong enough to cause permanent hemostasis. Further, typically once such mechanical hemostatic devices are at least partially deployed, they cannot be opened and closed repeatedly before the final release of the device, which may result in possible permanent deployment of the device at an undesirable location.

Still further, mechanical hemostatic devices typically are loaded, one at a time, within an introducer equipped to deliver and deploy the device. A first hemostatic device may be deployed, but if it becomes desirable to deliver and deploy a second hemostatic device, the introducer typically must be removed from the patient's body in order to load the second hemostatic device. The introducer then is loaded back into the patient's body to deploy the second hemostatic device, and the process is repeated for each subsequent device. However, the process of deploying only one hemostatic device at a time may become very time consuming and inconvenient, causing significant delays when it may be imperative to quickly stop bleeding.

SUMMARY

The present embodiments provide systems and methods for deploying at least one clip device. In each embodiment, multiple clips may be sequentially loaded and deployed using the delivery systems. Various clip designs and a loading cylinder are also disclosed.

In a first embodiment, the system comprises a first clip device having first and second arms. The first clip device and an associated sliding ring are configured to be selectively

advanced through a lumen of an inner catheter. Selective positioning of an outer catheter over a distal region of the inner catheter causes a distal region of the inner catheter to bow radially inward to form a constriction that securely engages the sliding ring of the first clip device. When the sliding ring is securely engaged, the first and second arms of the first clip device are movable longitudinally relative to the sliding ring, thereby allowing for partial closure and repositioning of the first clip device.

Advantageously, in this manner, any number of clip devices may be sequentially loaded into the lumen of the catheter and deployed, one at a time, without the need to remove the inner and outer catheters from the patient's body and individually re-load clip devices, thereby reducing operating time. Further, each of the clip devices advantageously may move between the open and closed states any number of times before final deployment.

In an alternative embodiment, a delivery system includes a catheter having proximal and distal ends, a lumen extending therebetween, and a tapered distal region. The catheter comprises a first inner diameter at a location proximal to the tapered distal region, and further has a second inner diameter at the distal end, wherein the second inner diameter is less than the first inner diameter. The sliding ring comprises an outer diameter that is less than the first inner diameter of the catheter and greater than the second inner diameter of the catheter. The tapered distal region of the catheter is flexible such that application of a predetermined distally-oriented forced imposed upon the sliding ring ejects the sliding ring from the distal end of the catheter. Upon ejection of the sliding ring from the distal end of the catheter, the sliding ring is dimensioned to abut the distal end of the catheter. At this time, proximal retraction of the first and second arms of the first clip device relative to the sliding ring moves the clip device between the open and closed states.

Other systems, methods, features and advantages of the invention will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be within the scope of the invention, and be encompassed by the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

FIGS. **1-5** are side-sectional views illustrating an exemplary delivery system and sequence of deployment for at least one clip device.

FIG. **6** is a perspective view illustrating features of a distal region of an inner catheter of the delivery system of FIGS. **1-5**.

FIGS. **7-9** are side-sectional views illustrating an alternative delivery system and sequence of deployment for at least one clip device.

FIG. **10** is a perspective view illustrating features of a distal region of a catheter of the delivery system of FIGS. **7-9**.

FIG. **11** is a side-sectional view of a loading cylinder that may be used in conjunction with clip delivery systems.

FIG. **12** is a perspective view of the clip device of FIGS. **7-9**.

FIG. **13** is a perspective view of an alternative clip device.

FIG. **14** is a perspective view of a further alternative clip device.

FIG. **15** is a perspective view of yet a further alternative clip device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the present application, the term "proximal" refers to a direction that is generally towards a physician during a medical procedure, while the term "distal" refers to a direction that is generally towards a target site within a patient's anatomy during a medical procedure.

Referring now to FIGS. **1-6**, a first embodiment of a clip device is shown, along with an exemplary system for delivery and deployment of at least one of the clip devices. In this embodiment, first and second clip devices **20***a* and **20***b* are provided. The first clip device **20***a* comprises a first arm **30***a* and a second arm **40***a*. The first arm **30***a* has a proximal end **32***a* and a distal end **34***a*, while the second arm **40***a* has a proximal end **42***a* and a distal end **44***a*. The proximal end **32***a* of the first arm **30***a* and the proximal end **42***a* of the second arm **40***a* are joined together by a proximal securement member **60***a*, which may comprise an adhesive, solder, weld, mechanical attachment device, or any other suitable mechanism, that joins the proximal ends **32***a* and **42***a* of the arms **30***a* and **40***a* together.

The clip device **20***a* further comprises a sliding ring **50***a*, which has an inner diameter that is slightly larger than an outer diameter of the first and second arms **30***a* and **40***a* combined. The proximal securement member **60***a* limits proximal movement of the sliding ring **50***a*. In use, the sliding ring **50***a* is dimensioned to slide over the first and second arms **30***a* and **40***a*, causing the arms to move to a closed position, as explained further in FIG. **4** below.

The distal ends **34***a* and **44***a* of the arms **30***a* and **40***a* are preferably bent in radially inward directions to form tips **38***a* and **48***a*, respectively, as best seen in FIG. **2**. The tips **38***a* and **48***a* are configured to grasp and/or pierce tissue. While two arms **30***a* and **40***a* are depicted in the embodiment of FIGS. **1-5**, it is contemplated that a greater number of arms may be used. For example, as explained in FIGS. **13-14** below, alternative clip devices **120***a*' and **120***a*" comprise three and four arms, respectively.

The first clip device **20***a* has a delivery state, an open state, and a closed state. In the delivery state, the first clip device **20***a* is disposed within a lumen **78** of an inner catheter **70**. The lumen **78** of the inner catheter **70** is dimensioned such that the distal ends **34***a* and **44***a* of the arms **30***a* and **40***a* are held adjacent to one another in the delivery state, as depicted in FIG. **1**.

In the open state, the distal ends **34***a* and **44***a* of the first and second arms **30***a* and **40***a*, respectively, tend to be spaced apart from one another, as shown in FIGS. **2-3**. The first and second arms **30***a* and **40***a* are biased to assume the open state when the distal ends **34***a* and **44***a* are no longer constrained by the inner catheter **70**. The distal ends **34***a* and **44***a* may be biased to assume the open state either due to the inherent resilient properties of the material forming the first and second arms **30***a* and **40***a*, or alternatively, the first and second arms **30***a* and **40***a* may be heat-set to assume the deployed configuration shown. The first and second arms **30***a* and **40***a* may be made from any suitable resilient material such as stainless steel, nitinol, plastic, and the like. Optionally, the arms of the clip may be formed of a resorbable material such as the magnesium alloy WE43, which can dissolve over time instead of needing to pass through a patient's gastrointestinal system. Further, the first and second arms **30***a* and **40***a* may have a cross-sectional shape that is round, square, rectangular, triangular, pie-shaped, truncated cone, and the like.

In the closed state, the sliding ring **50***a* is translated distally relative to the first and second arms **30***a* and **40***a*, as depicted in FIGS. **4-5** and explained further below. At this time, the distal ends **34***a* and **44***a* of the first and second arms **30***a* and **40***a*, respectively, are closed together and the tips **38***a* and **48***a* are configured to grasp tissue and facilitate tissue closure and hemostasis. The sliding ring **50***a* may lockingly engage the distal ends **34***a* and **44***a* of the first and second arms **30***a* and **40***a*, respectively, and may be sized so that it will not slide distally over the ends of the first and second arms **30***a* and **40***a* in the closed state. Optionally, one or more distal stop members, such as a solder or a mechanical member, may be disposed on the first arm **30***a* and/or the second arm **40***a* to limit distal advancement of the sliding ring **50***a*.

Referring still to FIGS. **1-5**, an exemplary system is described for delivery and deployment of at least one of the clip devices. The delivery system comprises the inner catheter **70** having the lumen **78**, as noted above, and further comprises an outer catheter **80** having a lumen **88**. In the embodiment of FIGS. **1-5**, first and second clip devices **20***a* and **20***b* are provided for sequential deployment, and the second clip device **20***b* is generally identical to the first clip device **20***a*.

The inner catheter **70** comprises an outer diameter that is less than an inner diameter of the outer catheter **80**, thereby allowing the inner catheter **70** to be longitudinally advanced within the lumen **88** of the outer catheter **80**. The inner catheter **70** further comprises an inner diameter that allows the first and second clip devices **20***a* and **20***b* to be loaded within the lumen **78** of the inner catheter **70**, as shown in FIG. **1**.

The inner catheter **70** comprises a distal end **74** and a flexible distal region **75**. The flexible distal region **75** may be selectively moved in a radially inward direction, for purposes described further below. Preferably, a plurality of slits **77** are formed in the distal end **74**, as shown in FIG. **6**, to permit the radial flexibility along the distal region **75**.

At least one wedge member **92** may be positioned along the flexible distal region **75** of the inner catheter **70**. In the embodiment shown, a plurality of wedge members **92** having a tapered shape are disposed between the inner catheter **70** and the outer catheter **80**, causing the flexible distal region **75** of the inner catheter **70** to move radially inward to form a constriction **79** when the outer catheter **80** is advanced against the wedge member **92**, as shown in FIGS. **3-4**. The wedge member **92** may comprise a biocompatible glue, plastic, metal or other suitable material, and may comprise other shapes besides the tapered shape depicted to accomplish the objectives described below. Alternatively, one or more wedge members **92** may be formed as an integral portion of the inner catheter **70** along the distal region **75**.

The outer catheter **80** may comprise a rigid or substantially rigid material, such as stainless steel or plastic materials, which substantially prohibits radial outward movement of the wedge member **92** and the flexible distal region **75** of the inner catheter **70** when a distal end **84** of the outer catheter **80** covers these regions, as shown in FIGS. **3-4**. However, when the distal end **84** of the outer catheter **80** is retracted proximally beyond the wedge member **92** and the flexible distal region **75** of the inner catheter **70**, the flexible distal region **75** may move radially outward and the constriction **79** may be removed, as depicted in FIG. **5** below.

In one exemplary method, the first and second clip devices **20***a* and **20***b* are loaded sequentially such that the first clip device **20***a* is loaded distal to the second clip device **20***b* within the lumen **78** of the inner catheter **70**, as shown in FIG.

1. A stylet **90** may be positioned in the lumen **78** at a location proximal to the second clip device **20***b*.

In one embodiment, the first and second clip devices **20***a* and **20***b* each comprise proximal retainers **64***a* and **64***b*, respectively. The proximal retainers **64***a* and **64***b* may be in the form of loop members having outer diameters that are smaller than the inner diameter of the inner catheter **70**. In use, the first and second clip devices **20***a* and **20***b* may be loaded within the inner catheter **70** such that the distal ends **34***b* and **44***b* of the second clip device **20***b* securely engage the proximal retainer **64***a* of the first clip device **20***a* when the inner catheter **70** is positioned over the connection as shown in FIGS. **1-4**. When the inner catheter **70** is no longer positioned over this connection, as shown in FIG. **5**, the first and second clip devices **20***a* and **20***b* may disengage from one another, as explained below.

The stylet **90** may comprise a retainer **92**, such as a hook member, that engages the proximal retainer **64***b* at the proximal end of the second clip device **20***b* when the inner catheter **70** is positioned over this connection, as shown in FIGS. **1-5**. Accordingly, proximal and distal advancement of the stylet **90** causes a corresponding movement of the first and second clip devices **20***a* and **20***b*.

It should be noted that while two clip devices are shown in this example, any number may be used and sequentially loaded into the inner catheter **70** in an abutting manner distal to the stylet **90**. Moreover, while one exemplary retainer arrangement is shown in the form of a hook and loop connection, various other retainer arrangements are possible. By way of example, alternative retainer arrangements to couple the stylet **90** to the second clip device **20***b*, and/or to couple the first and second clip devices **20***a* and **20***b* together, are described in U.S. Pat. Pub. No. 2007/0282355, the disclosure of which is hereby incorporated by reference in its entirety.

The stylet **90**, the first clip device **20***a* and the second clip device **20***b* are loaded into the inner catheter **70** as shown in FIG. **1**. Optionally, at this time, the outer catheter **80** may be positioned over the inner catheter **70**, as shown in FIG. **3**, such that the constriction **79** is formed via the wedge member **92**. The constriction **79** may prevent the first and second arms **30***a* and **40***a* of the first clip device from extending distal to the inner catheter **70** to reduce the likelihood of inadvertent piercing during delivery.

Referring to FIG. **2**, the outer catheter **80** is positioned proximally relative to the inner catheter **70**, thereby exposing the distal region **75** of the inner catheter **70**. The stylet **90** is advanced distally, relative to the inner catheter **70** and the outer catheter **80**, to cause distal advancement of the second clip device **20***b* and corresponding distal advancement of the first clip device **20***a* in an abutting manner. The stylet **90** is advanced distally until the sliding ring **50***a* of the first clip device **20***a* is aligned with the distal region **75** of the inner catheter **70**, as shown in FIG. **2**. At this time, the distal ends **34***a* and **44***a* of the first and second arms **30***a* and **40***a*, respectively, of the first clip device **20***a* are advanced distally beyond the distal end **74** of the catheter **70**, and when unconstrained, tend to bow in a radially outward direction spaced apart from one another, as depicted in FIG. **2**.

Referring to FIG. **3**, in a next step, the outer catheter **80** is advanced distally relative to the inner catheter **70**, thereby engaging the wedge members **92** and urging the distal end **74** of the inner catheter **70** into engagement with the sliding ring **50***a*. A friction fit is achieved such that the sliding ring **50***a* is held steady. At this time, the stylet **90** may be proximally and distally advanced, thus causing corresponding movement of the first and second arms **30***a* and **40***a* relative to the sliding ring **50***a*. Thus, the sliding ring **50***a* is held steady while the first and second arms **30***a* and **40** disposed therein are advanced or retracted as desired.

In accordance with one aspect, a physician need not deploy the first clip device **20***a* at this time. Rather, the first clip device **20***a* may be moved between the open state of FIG. **3**, and a state that is at least partially closed, any number of times before final deployment. For example, a physician may at least partially close the first clip device **20***a* by proximally retracting the stylet **90**, and therefore the first and second arms **30***a* and **40***a*, relative to the sliding ring **50***a*, thus forcing the distal ends **34***a* and **44***a* closer together. However, before the distal ends **34***a* and **44***a* are locked closed within the sliding ring **50***a*, the physician may distally advance the stylet **90**, thus distally advancing the first and second arms **30***a* and **40***a* relative to the sliding ring **50***a* and re-opening the first clip device **20***a*, e.g., for alternative positioning or grasping. Advantageously, in this manner, the first clip device **20***a* may move between the open and closed states any number of times before final deployment.

Referring now to FIG. **4**, if a physician wishes to securely close the first clip device **20***a* with tissue therein, the stylet **90** and the first clip device **20***a* are retracted tightly relative to the inner catheter **70** that is holding the sliding ring **50***a*. Alternatively, the inner catheter **70** and outer catheter **80** may be advanced distally in tandem, while the stylet **90** is held steady. The result in either case is that the sliding ring **50***a* is translated distally relative to the first and second arms **30***a* and **40***a* with enough force, as shown in FIG. **4**, thereby securely closing the first clip device **20***a*.

Referring now to FIG. **5**, in a next step, the outer catheter **80** is proximally retracted with respect to the inner catheter **70**, such that the distal end **84** of the outer catheter **80** is positioned proximal to the wedge member **92**. At this time, the wedge member **92** is no longer radially constrained and the flexible distal region **75** of the inner catheter **70** may move radially outward to remove the constriction **79**, as depicted in FIG. **5**. The sliding ring **50***a* is no longer engaged in a friction fit with the inner catheter **70**.

The stylet **90** is then advanced distally relative to the inner catheter **70** to cause the distal ends **34***b* and **44***b* of the first and second arms **30***b* and **40***b*, respectively, of the second clip device **20***b* to extend distal to the inner catheter **70**. At this time, the connection between the first and second arms **30***b* and **40***b* of the second clip device **20***b* and the proximal retainer **64***a* of the first clip device **20***a* is exposed, thereby allowing the first and second clip devices **20***a* and **20***b* to detach from engagement with one another, as shown in FIG. **5**.

After deployment of the first clip device **20***a*, but before deployment of the second clip device **20***b*, the sliding ring **50***b* of the second clip device **20***b* may be aligned with the distal region **75** of the inner catheter **70**, in the manner explained in FIG. **2** above for the first clip device **20***a*. The sequence of deployment described in FIGS. **2-5** then may be carried out for the second clip device **20***b*. Advantageously, in this manner, any number of clip devices may be sequentially loaded into the lumen **78** of the inner catheter **70** and deployed, one at a time, without the need to remove the inner and outer catheters **70** and **80** from the patient's body and individually re-load clip devices, thereby saving operating time.

Referring to FIG. **6**, and as noted above, the flexible distal region **75** of the inner catheter **70** may be selectively moved in a radially inward direction by providing a plurality of slits **77** formed in the flexible distal region **75**. In the embodiment shown, four slits **77** are formed in the distal end **74** of the catheter **70** and extend in tapered manner in a distal to proximal direction. The four slits **77** may be radially spaced apart around the circumference of the catheter **70**. The one or more wedge members **92** may be attached to the flexible distal region **75** at one or more locations between the slits **77**. While four illustrative tapered slits **77** are shown in FIG. **6**, it will be appreciated that greater or fewer slits may be employed, and they may comprise different shapes and configurations than depicted.

Referring now to FIGS. **7-10**, an alternative delivery system and sequence of deployment for at least one clip device is shown. In FIGS. **7-10**, an alternative first clip device **120*a*** is similar to the first clip device **20*a*** described above, with a main exception that proximal ends **132*a*** and **142*a*** of first and second arms **130*a*** and **140*a***, respectively, are integrally formed into a proximal retainer **164*a*** in the shape of a loop member, and therefore the proximal securement member **60*a*** of FIGS. **1-5** is omitted. In this manner, the first clip device **120*a*** may be formed from one continuous wire that is looped around at its proximal end, and where the continuous wire is bent to form distal ends **134*a*** and **144*a***, as shown in FIG. **7** and described further in FIG. **12** below.

The proximal retainer **164*a*** in the shape of the loop member has an outer diameter that is larger than the inner diameter of the sliding ring **50*a***, thereby limiting proximal movement of the sliding ring **50*a***. As in the embodiment of FIGS. **1-5**, the sliding ring **50*a*** is otherwise dimensioned to slide over the first and second arms **130*a*** and **140*a***, toward the distal ends **134*a*** and **134*b*** of the first and second arms **130*a*** and **140*a***, respectively, causing the arms to move to a closed position. The first clip device **120*a*** has a delivery state, an open state, and a closed state, similar to the first clip device **20*a*** described above.

The alternative delivery system of FIGS. **7-10** comprises a catheter **170** having a lumen **178**, and has an inner diameter that is generally larger than an outer diameter of the first and second clip devices **20*a*** and **20*b*** in the delivery state, thereby allowing the first and second clip devices **20*a*** and **20*b*** to be loaded within the lumen **78** of the catheter **70** as shown in FIG. **1**. Notably, in this embodiment, an outer catheter is omitted.

The catheter **170** comprises a distal end **174** and a tapered distal region **175**. Preferably, at least one slit **177** is formed in the tapered distal region **175**, as shown in FIG. **10**, to permit the radial flexibility along the distal region **175**.

In one exemplary method, the first and second clip devices **120*a*** and **120*b*** may be loaded sequentially such that the first clip device **120*a*** is loaded distal to the second clip device **120*b*** within the lumen **178** of the catheter **170**, as shown in FIG. **7**. The stylet **90** may be positioned in the lumen **178** at a location proximal to the second clip device **120*b***. In use, the first and second clip devices **120*a*** and **120*b*** may be loaded within the catheter **170** such that the distal ends **134*b*** and **144*b*** of the second clip device **120*b*** securely engage the proximal retainer **164*a*** of the first clip device **120*a***. Further, the retainer **92** of the stylet **90** engages the proximal retainer **164*b*** at the proximal end of the second clip device **120*b***, as shown in FIG. **7**. Accordingly, proximal and distal advancement of the stylet **90** causes a corresponding movement of the first and second clip devices **120*a*** and **120*b***.

Notably, the catheter **170** has a first inner diameter D_1 at a location proximal to the tapered distal region **175**, and has a smaller second inner diameter D_2 at the distal end **174**, as shown in FIG. **10**, such that the taper reduces the inner diameter from D_1 to D_2. The sliding ring **50*a*** has an outer diameter having a size dimension between the first and second inner diameters D_1 to D_2 of the catheter **170**. In the delivery state shown in FIG. **7**, absent significant forces imposed thereon, the tapered distal region **175** serves to retain the first clip device **120*a*** inside of the catheter **170** and prevents inadvertent piercing by the arms **130*a*** and **140*a***.

Referring to FIG. **8**, in a next step, the stylet **90** is advanced distally, relative to the catheter **170**, to cause distal advancement of the second clip device **120*b*** and corresponding distal advancement of the first clip device **120*a*** in an abutting manner. The stylet **90** is advanced distally until the sliding ring **50*a*** of the first clip device **120*a*** abuts the tapered distal region **175** and is ultimately advanced distal to the tapered distal region **175** with a sufficient force. The slit **177** of the tapered distal region **175** allows the distal end **174** of the catheter **170** to flex upon application of the sufficient force imposed by the sliding ring **50*a***, and further, the tapered distal region **175** may be formed of a material, such as molded plastic, that facilitates such flexing upon application of the sufficient force by the sliding ring **50*a***. At this time, the distal ends **134*a*** and **144*a*** of the arms **130*a*** and **140*a***, respectively, of the first clip device **120*a*** are advanced distally beyond the distal end **174** of the catheter **170**, and when unconstrained, tend to bow in a radially outward direction spaced apart from one another, as depicted in FIG. **8**.

While the sliding ring **50*a*** is disposed just distal to the tapered distal region **175** of the catheter **170**, the proximal retainer **164*a*** of the first clip device **120*a*** is retained within the lumen **178** of the catheter **170**, as shown in FIG. **8**. The tapered distal region **175** of the catheter **170** may be biased such that it tends to close around the proximal retainer **164*a*** of the first clip device **120*a***. At this time, the distal end **174** of the catheter **170** abuts a proximal edge of the sliding ring **50*a***, as depicted in FIG. **8**. Since the second inner diameters D_2 of the catheter **70** is less than an outer diameter of the sliding ring **50*a***, the sliding ring **50*a*** is prevented from being pulled back into the lumen **178** of the catheter **170**.

The stylet **90** may be proximally retracted to at least partially close the first clip device **120*a***. However, before the distal ends **134*a*** and **144*a*** are locked closed within the sliding ring **50*a***, the physician may proximally or distally advance the stylet **90** gently, thus partially closing and re-opening the first and second arms **130*a*** and **140*a***.

Referring to FIG. **9**, if a physician wishes to securely close the first clip device **120*a*** with tissue therein, the stylet **90** and the first clip device **120*a*** are retracted tightly relative to the catheter **170**. Alternatively, the catheter **170** may be advanced while the stylet **90** is held steady. The result in either case is that the sliding ring **50*a*** is translated distally relative to the first and second arms **130*a*** and **140*a***, as shown in FIG. **9**, thereby securely closing the first clip device **120*a***.

Subsequently, the stylet **90** is then advanced distally relative to the catheter **170** to cause the distal ends **134*b*** and **144*b*** of the arms **130*b*** and **140*b***, respectively, of the second clip device **120*b*** to extend distal to the catheter **170**. At this time, the connection between the first and second arms **130*b*** and **140*b*** of the second clip device **120*b*** and the proximal retainer **164*a*** of the first clip device **120*a*** is exposed, thereby allowing the first and second clip devices **120*a*** and **120*b*** to detach from engagement with one another in a manner similar to the embodiment of FIG. **5**.

The sequence of deployment described in FIGS. **7-9** then may be carried out for the second clip device **120*b***. Advantageously, in this manner, any number of clip devices may be sequentially loaded into the lumen **178** of the catheter **170** and deployed, one at a time, without the need to remove the catheter **170** from the patient's body and individually re-load clip devices, thereby saving operating time.

Referring now to FIG. **11**, a loading cylinder **190** may be used in conjunction with either the embodiment of FIGS. **1-6** or FIGS. **7-10** to facilitate fast and efficient loading or reloading of one or more clip devices. In the embodiment of FIG. **11**, the loading cylinder **190** comprises proximal and distal ends **192** and **194**, respectively, and a lumen **198** extending therebetween. The loading cylinder **190** may comprises inner and outer diameters that are identical to inner and outer diameters of the inner catheter **70** of FIGS. **1-6** or the catheter **170** of FIGS. **7-10**. Optionally, an engagement mechanism (not shown) may be provided to selectively couple the distal end **194** of the loading cylinder **190** with the proximal end **172** of the catheter **170**, to thereby ensure a correct alignment between the lumen **198** of the loading cylinder **190** and the lumen **178** of the catheter **170**.

In the example of FIG. **11**, two additional clip devices **120***c* and **120***d*, which are identical to the clip devices **120***a* and **120***b* of FIGS. **7-9**, are loaded into the lumen **198** of the loading cylinder **190** as shown. The proximal retainer **164***d* of the clip device **120***d* may extend just outside of the proximal end **192** of the loading cylinder **190**, as shown in FIG. **11**, for subsequent engagement with a retainer **92'** of an alternative stylet **90'**. The alternative stylet **90'** is similar to the stylet **90** described above, with an exception that the retainer **92'** comprises arms **95** and **96**, which are similar in structure to the distal ends **134***a* and **144***a* of the first clip device **120***a*.

In use, a physician may deploy the clip devices **120***a* and **120***b* in the manner described in FIGS. **7-9** above. The loading cylinder **190**, carrying additional clip devices **120***c* and **120***d*, may be provided in the operating room. If the additional clip devices **120***c* and **120***d* are needed, the stylet **90'** is retracted from within the lumen **178** of the catheter **170**, and may be withdrawn towards a sheath **98** as depicted in FIG. **11**. The distal end **194** of the loading cylinder **190** then is aligned with the proximal end **172** of the catheter **170**, such that the lumen **198** of the loading cylinder **190** is aligned with the lumen **178** of the catheter **170**. The arms **95** and **96** of the retainer **92'** of the stylet **90'** then are joined to the proximal retainer **164***d* of the clip device **120***d* and urged distally into the loading cylinder **190**. Distal advancement of the stylet **90'** causes corresponding distal advancement of the clip devices **120***c* and **120***d* through the lumen **178** of the catheter **170**, and the deployment of the clip devices **120***c* and **120***d* may be carried out in the manner described above. Advantageously, the endoscope and catheters can remain in place within the body of the patient, retaining access to the bleeding site, and facilitating a faster procedure. The catheters **70** and **170** described above can be reloaded as many times as needed using one or more loading cylinders **190**. Moreover, different loading cylinders **190** can be provided with different clip styles.

Referring now to FIGS. **12-15**, features of various possible clip designs are shown. In FIG. **12**, the clip device **120***a* of the embodiment of FIGS. **7-10** is shown in isolation. In one embodiment, the clip device **120***a* has a length in the delivery state of between about 10 mm to about 25 mm. In the open state, the distance between the distal ends **134***a* and **144***a* of the first and second arms **130***a* and **140***a*, respectively, may be between about 6 mm to about 10 mm. The wire forming the clip device **120***a* may comprise a flat wire having a width of about 0.8 mm to about 1.0 mm, and a thickness of about 0.1 mm to about 0.2 mm. When used in conjunction with a delivery system as shown in FIGS. **1-6** or FIGS. **7-10**, the clip device **120***a* and associated sliding ring **50***a* can fit down an endoscope channel having a 2.8 mm or 3.2 mm diameter. As noted above, the clip device **120***a* can be formed of any suitable material such as nitinol or another material that may be biased to assume the open state shown in FIG. **12** upon removal from a delivery catheter, and optionally may be formed of a resorbable material.

In FIG. **13**, an alternative clip device **120***a'* is formed from a wire that is bent to form the first and second arms **130***a* and **140***a*, as explained in FIGS. **7-9** and FIG. **12** above, however an additional wire segment is provided and forms a third arm **150***a* having a proximal end **152***a* and a distal end **154***a*. A three-prong clip device **120***a'* therefore is provided. The proximal end **152***a* of the third arm **150***a* may be soldered to a portion of the loop formed by the proximal ends **132***a* and **142***a* of the arms **130***a* and **140***a*, respectively, thereby forming a proximal retainer **164***a*. In a further alternative, a clip device may be similar to the clip device **120***a'*, but may comprise a fourth arm, whereby the four arms may be equally spaced apart about 90 degrees from one another, or variably spaced apart at other distances from one another.

In FIG. **14**, an alternative clip device **120***a"* is substantially identical to the clip device **120***a*, with the exception that an additional wire is disposed inward of the wire forming the first and second arms **130***a* and **140***a*. The additional wire forms third and fourth arms **130***a"* and **140***a"* having proximal ends **132***a"* and **142***a"*, respectively. The proximal ends **132***a"* and **142***a"* form a loop member disposed inside of the loop member formed by the proximal ends **132***a* and **142***a* of the first and second arms **130***a* and **140***a*, respectively, as shown in FIG. **14**, to form a proximal retainer **164***a"*. Further, the third and fourth arms **130***a"* and **140***a"* have distal ends **134***a"* and **144***a"*, which may be slightly offset from the distal ends **134***a* and **144***a* of the first and second arms **130***a* and **140***a*, respectively, as shown in FIG. **14**.

In FIG. **15**, an alternative clip device **220** is similar to the clip device **120***a* in that one wire is bent to form first and second arms **230** and **240** having proximal ends **232** and **234**, respectively, which are coupled together to form a proximal retainer **264** in the shape of a loop member. The first and second arms **230** and **240** further comprise distal ends **234** and **244**, respectively. In this embodiment, the wire forming the first and second arms comprises a round cross-sectional shape. In order to provide a larger and sharper surface area to engage tissue, grasping members **250***a* and **250***b* are coupled to exterior surfaces of the distal ends **234** and **244** of the first and second arms **230** and **240**, respectively. The grasping members **250***a* and **250***b* may be coupled to the first and second arms **230** and **240** using a solder, weld, mechanical connection, or other suitable technique. Preferably, the grasping members **250***a* and **250***b* comprise sharpened distal tips **255** that are bent radially inward to securely engage tissue. It will be appreciated that where flat wire cross-sections are depicted herein, round wire cross-sections may be provided, and vice versa.

While various embodiments of the invention have been described, the invention is not to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

I claim:

1. A system for deploying at least one clip device, the system comprising:

a first clip device having first and second arms, wherein distal ends of the first and second arms tend to be spaced apart from each other when the first clip device is in an open state, and wherein the distal ends of the first and second arms are adjacent to each other when the first clip device is in a closed state;

a sliding ring being movable between a first position when the first clip device is in the open state and a second position to hold the first and second arms of the first clip device in the closed state;

an inner catheter having a lumen, wherein the first clip device and the sliding ring are configured to be selectively advanced through the lumen of the inner catheter; and

an outer catheter having a lumen, wherein the inner catheter is configured for longitudinal movement with respect to the lumen of the outer catheter,

wherein selective positioning of the outer catheter over a distal region of the inner catheter causes the distal region of the inner catheter to bow radially inward to form a constriction that selectively engages the sliding ring of the first clip device using a friction fit, so that the sliding ring does not move either proximally or distally.

2. The system of claim **1**, wherein the first and second arms of the first clip device are movable longitudinally relative to the sliding ring while the sliding ring is engaged by the constriction of the inner catheter, to permit selective movement of the first and second arms between the open state and a partially closed state.

3. The system of claim **1**, further comprising at least one wedge member disposed at the distal region of the inner catheter, wherein the outer catheter is configured to selectively engage the wedge member to form the constriction when the outer catheter is positioned over the distal region of the inner catheter.

4. The system of claim **3**, wherein the distal region of the inner catheter comprises at least one slit formed in a distal end of the inner catheter, wherein the at least one slit facilitates movement of the distal region of the catheter in a radially inward direction.

5. The system of claim **1**, wherein multiple clip devices are configured to be loaded in a sequential manner within the lumen of the inner catheter at the same time, and further are configured to be individually and selectively deployed from a distal end of the inner catheter.

6. The system of claim **5** further comprising:

a second clip device having first and second arms, wherein distal ends of the first and second arms tend to be spaced apart from each other when the second clip device is in an open state, and wherein the distal ends of the first and second arms are adjacent to each other when the second clip device is in a closed state; and

a stylet disposed for longitudinal movement within the lumen of the inner catheter,

wherein the second clip device is configured to be disposed within the lumen of the inner catheter at a location distal to the stylet during delivery, and wherein the first clip device is configured to be disposed in the lumen of the inner catheter at a location distal to the second clip device during delivery,

wherein distal advancement of the stylet is adapted to cause distal advancement of the first and second clip devices to selectively deploy the first clip device and, subsequently, selectively deploy the second clip device.

7. The system of claim **6** wherein the first clip device comprises a proximal retainer adapted to securely engage the distal ends of the first and second arms of the second clip device within the lumen of the inner catheter, wherein the proximal retainer comprises a continuous loop formed by proximal ends of the first and second arms of the first clip device.

8. The system of claim **6** wherein proximal ends of the first and second arms of the first clip device are joined together by a proximal securement member, and wherein a proximal retainer is coupled to the proximal securement member and configured for engagement with the distal ends of the first and second arms of the second clip device within the lumen of the inner catheter.

9. A system for deploying at least one clip device, the system comprising:

a first clip device having first and second arms, wherein distal ends of the first and second arms are biased towards an open state in which they are spaced apart from each other, and wherein the distal ends of the first and second arms are adjacent to each other when the first clip device is in a closed state;

a sliding ring being movable between a first position when the first clip device is in the open state and a second position to hold the arms of the first clip device in the closed state; and

a catheter having proximal and distal ends, a lumen extending therebetween, and a tapered distal region, wherein the catheter comprises a first inner diameter at a location proximal to the tapered distal region, and further has a second inner diameter at the distal end, wherein the second inner diameter is less than the first inner diameter,

wherein the sliding ring comprises an outer diameter that is less than the first inner diameter of the catheter and greater than the second inner diameter of the catheter,

wherein the tapered distal region of the catheter is integral to the catheter, is directly adjacent to the first clip device in a delivery state, and is flexible such that application of a predetermined distally-oriented force imposed by the sliding ring ejects the sliding ring from the distal end of the catheter, and

wherein there is no outer catheter surrounding the tapered distal region of the catheter.

10. The system of claim **9** wherein, upon ejection of the sliding ring from the distal end of the catheter, the sliding ring is dimensioned to abut the distal end of the catheter.

11. The system of claim **10** wherein, upon ejection of the sliding ring from the distal end of the catheter, proximal retraction of the first and second arms of the first clip device relative to the sliding ring moves the first clip device between the open and closed states.

12. The system of claim **9** wherein the tapered distal region of the catheter comprises at least one slit formed in the distal end of the catheter, wherein the at least one slit facilitates movement of the tapered distal region of the catheter in a radially outward direction.

13. The system of claim **9** wherein multiple clip devices are configured to be loaded in a sequential manner within the lumen of the catheter at the same time, and further are configured to be individually and selectively deployed from the distal end of the catheter.

14. The system of claim **13** further comprising:

a second clip device having first and second arms, wherein distal ends of the first and second arms tend to be spaced apart from each other when the second clip device is in an open state, and wherein the distal ends of the first and second arms are adjacent to each other when the second clip device is in a closed state; and

a stylet disposed for longitudinal movement within the lumen of the catheter,

wherein the second clip device is configured to be disposed in the lumen of the catheter at a location distal to the stylet during delivery, and wherein the first clip device is configured to be disposed in the lumen of the catheter at a location distal to the second clip device during delivery,

wherein distal advancement of the stylet is adapted to cause distal advancement of the first and second clip devices to selectively deploy the first clip device and, subsequently, selectively deploy the second clip device.

15. The system of claim **14**, wherein the first clip device comprises a proximal retainer adapted to securely engage the distal ends of the first and second arms of the second clip device within the lumen of the catheter, wherein the proximal retainer is disposed at a location proximal to the sliding ring, and wherein the proximal retainer is configured to be retained within the lumen of the catheter when the sliding ring is ejected distal to the catheter.

16. The system of claim **15**, wherein the proximal retainer comprises a continuous loop formed by proximal ends of the first and second arms of the first clip device.

17. A system for deploying at least one clip device, the system comprising:

a first clip device having first and second arms, wherein distal ends of the first and second arms tend to be spaced apart from each other when the first clip device is in an open state, and wherein the distal ends of the first and second arms are adjacent to each other when the first clip device is in a closed state;

a sliding ring being movable between a first position when the first clip device is in the open state and a second position to hold the first and second arms of the first clip device in the closed state;

an inner catheter having a lumen, wherein the first clip device and the sliding ring are configured to be selectively advanced through the lumen of the inner catheter; and

an outer catheter having a lumen, wherein the inner catheter is configured for longitudinal movement with respect to the lumen of the outer catheter,

wherein selective positioning of the outer catheter over a distal region of the inner catheter causes the distal region of the inner catheter to bow radially inward to form a constriction that selectively engages the sliding ring of the first clip device using a friction fit,

wherein the sliding ring has first and second ends, and the constriction engages the sliding ring between the first and second ends.

18. The system of claim **17**, wherein the first and second arms of the first clip device are movable longitudinally relative to the sliding ring while the sliding ring is engaged by the constriction of the inner catheter, to permit selective movement of the first and second arms between the open state and a partially closed state.

19. The system of claim **17**, further comprising at least one wedge member disposed at the distal region of the inner catheter, wherein the outer catheter is configured to selectively engage the wedge member to form the constriction when the outer catheter is positioned over the distal region of the inner catheter.

20. The system of claim **19**, wherein the distal region of the inner catheter comprises at least one slit formed in a distal end of the inner catheter, wherein the at least one slit facilitates movement of the distal region of the catheter in a radially inward direction.

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